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10 Eli Lilly and Company, a corporation

11 UNITED STATES DISTRICT COURT

12 NORTHERN DISTRICT OF CALIFORNIA

13 BARBARA MURRAY, JAMES VINSON,
ARETHA WILLIAMS,

14 Plaintiffs,

15 vs.

16 ELI LILLY AND COMPANY,

17 Defendant.

18 No. C 06-1607 CW

19 Before the Honorable Claudia Wilken

20 **DEFENDANT ELI LILLY AND
COMPANY, A CORPORATION'S
ANSWER TO COMPLAINT AND JURY
DEMAND**

21
22 Defendant Eli Lilly and Company ("Lilly"), a corporation, hereby answers plaintiffs'
23 Complaint ("Complaint"), as filed in the U.S. District Court for the Northern District of California,
24 Action No. C 06-1607 CW, by and through the undersigned counsel. The following numbered
25 paragraphs correspond to the numbered paragraphs in plaintiffs' Complaint.
26
27
28

No.: C 06-1607 CW

NATURE OF THE CASE

1. Lilly denies the allegations contained in Paragraph 1 of the Complaint.

JURISDICTION AND VENUE

2. Lilly denies the allegations contained in Paragraph 2 of the Complaint, except admits only that (i) subject matter jurisdiction exists pursuant to 28 U.S.C. § 1332(a); and (ii) at certain times, Lilly has been authorized to do business in the State of California and in this judicial district.

THE PARTIES

Plaintiffs

3. Lilly denies the allegations contained in Paragraph 3 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 3 of the Complaint regarding plaintiff Barbara Murray's residency.

4. Lilly denies the allegations contained in Paragraph 4 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 4 of the Complaint regarding plaintiff James Vinson's residency.

5. Lilly denies the allegations contained in Paragraph 5 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 5 of the Complaint regarding plaintiff Aretha Williams' residency.

Defendant

6. Lilly denies the allegations contained in Paragraph 6 of the Complaint, except admits that (i) it is a corporation organized and existing under the laws of the State of Indiana, with its principal place of business in Indianapolis, Indiana; (ii) at certain times, it has been authorized to do business in the State of California; and (iii) it researched, tested, developed, manufactured, marketed, and sold Zyprexa® to independent pharmaceutical wholesalers for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with warnings approved by the Food and Drug Administration (“FDA”) regarding the risks and benefits of the medication.

FACTUAL ALLEGATIONS

7. Lilly denies the allegations contained in Paragraph 7 of the Complaint, except admits that (i) Zyprexa is a psychotropic agent that belongs in the thienobenzodiazepine class of medications also known as “atypical antipsychotics”; (ii) Zyprexa is approved by the FDA for the treatment of schizophrenia, the treatment of acute mixed or manic episodes associated with Bipolar I Disorder, and maintenance monotherapy for Bipolar Disorder; and (iii) the combination of Zyprexa with Lithium or Valproate is indicated for the short-term treatment of acute manic episodes associated with Bipolar I Disorder.

8. Lilly denies the allegations contained in Paragraph 8 of the Complaint, except admits that it researched, tested, developed, manufactured, marketed, and sold Zyprexa to independent pharmaceutical wholesalers for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with warnings approved by the FDA regarding the risks and benefits of the medication.

9. Lilly denies the allegations contained in Paragraph 9 of the Complaint, except admits

1 that it researched, tested, developed, manufactured, marketed, and sold Zyprexa to independent
2 pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance
3 with applicable laws and regulations, and for its approved indications with FDA-approved warnings
4 regarding the risks and benefits of the medication.

5
6 10. Lilly denies the allegations contained in Paragraph 10 of the Complaint.

7
8 11. Lilly denies the allegations contained in Paragraph 11 of the Complaint, except
9 admits that it marketed and sold Zyprexa to independent pharmaceutical wholesalers, including in
10 the State of California, for use only upon prescription by a licensed physician, in accordance with
11 applicable laws and regulations, and for its approved indications with FDA-approved warnings
12 regarding the risks and benefits of the medication.

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14 12. Lilly denies the allegations contained in Paragraph 12 of the Complaint, except
15 admits that it marketed and sold Zyprexa to independent pharmaceutical wholesalers for use only
16 upon prescription by a licensed physician, in accordance with applicable laws and regulations, and
17 for its approved indications with FDA-approved warnings regarding the risks and benefits of the
18 medication.

19
20 13. Lilly denies the allegations contained in Paragraph 13 of the Complaint.

21
22 14. Lilly is without knowledge or information as to plaintiffs' meaning of the term "total
23 profits," and therefore denies the allegations contained in Paragraph 14 of the Complaint, except
24 Lilly admits that the sales figures for Zyprexa are disclosed in its filings with the Securities and
25 Exchange Commission ("SEC"), which are publicly available, and denies any characterization or
26 interpretation inconsistent with these documents when read in context and in their entirety.

27
28 15. Lilly denies the allegations contained in Paragraph 15 of the Complaint, except (A)

1 (i) admits that medical literature reporting on medical research involving Zyprexa is published in
2 multiple medical journals, but denies plaintiffs' description of the unidentified "medical literature,"
3 "reports," and "studies" to the extent that it conflicts with such literature, reports, and studies;
4 (ii) denies the allegations contained in Paragraph 15 of the Complaint to the extent that the
5 allegations are inconsistent with the referenced report contained in the October 15, 1998 publication
6 of the Society of Biological Psychiatry when assessed in context and in its entirety; (iii) denies
7 plaintiffs' description of the 2003 Duke University Medical Center Study to the extent that the
8 allegations in Paragraph 15 are inconsistent with the findings and conclusions of the Duke
9 University Medical Center study when assessed in context and in their entirety; and (B) admits that it
10 has marketed Zyprexa to physicians in accordance with applicable laws and regulations, with
11 adequate communication of the known risks, and with adequate warnings commensurate with the
12 risk and gravity of the possible side effects from its use.

13
14 16. Lilly denies the allegations contained in Paragraph 16 of the Complaint, except is
15 without knowledge or information sufficient to form a belief as to the allegations relating to
16 plaintiffs' physicians' reliance.

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18 17. Lilly denies the allegations contained in Paragraph 17 of the Complaint.

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20 18. Lilly denies the allegations contained in Paragraph 18 of the Complaint.

21
22 19. Lilly denies the allegations contained in Paragraph 19 of the Complaint.

23
24 20. Lilly denies the allegations contained in Paragraph 20 of the Complaint, except is
25 without knowledge or information sufficient to form a belief as to the allegations relating to
26 plaintiffs' and plaintiffs' physicians.

FIRST CAUSE OF ACTION

[Strict Product Liability]

[Failure to Warn]

21. Lilly incorporates by reference its responses to Paragraphs 1 through 20 of the Complaint.

22. Lilly denies the allegations contained in Paragraph 22 of the Complaint, except admits that it researched, tested, developed, manufactured, marketed, and sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication.

23. Lilly denies the allegations contained in Paragraph 23 of the Complaint.

24. Lilly denies the allegations contained in Paragraph 24 of the Complaint.

25. Lilly denies the allegations contained in Paragraph 25 of the Complaint.

26. Lilly denies the allegations contained in Paragraph 26 of the Complaint.

SECOND CAUSE OF ACTION

[Strict Product Liability]

[Pursuant to Restatement Second of Torts § 402A (1965)]

27. Lilly incorporates by reference its responses to Paragraphs 1 through 26 of the Complaint.

28. Lilly denies the allegations contained in Paragraph 28 of the Complaint, except admits that it researched, tested, developed, manufactured, marketed, and sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication.

29. Lilly denies the allegations contained in Paragraph 29 of the Complaint.

30. Lilly denies the allegations contained in Paragraph 30 of the Complaint.

31. Lilly denies the allegations contained in Paragraph 31 of the Complaint.

32. Lilly denies the allegations contained in Paragraph 32 of the Complaint.

33. Lilly denies the allegations contained in Paragraph 33 of the Complaint.

34. Lilly denies the allegations contained in Paragraph 34 of the Complaint.

THIRD CAUSE OF ACTION

[Negligence]

35. Lilly incorporates by reference its responses to Paragraphs 1 through 34 of the Complaint.

36. Lilly denies the allegations contained in Paragraph 36 of the Complaint, except admits that it had a duty to exercise reasonable care in the research, testing, development, manufacturing, labeling, marketing, and sale of Zyprexa. Lilly denies that it breached such a duty.

37. Lilly denies the allegations contained in Paragraph 37 of the Complaint.

1 38. Lilly denies the allegations contained in Paragraph 38 of the Complaint.
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3 39. Lilly denies the allegations contained in Paragraph 39 of the Complaint.
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5 40. Lilly denies the allegations contained in Paragraph 40 of the Complaint.
6

7 **FOURTH CAUSE OF ACTION**

8 **[Breach of Express Warranty]**

9 41. Lilly incorporates by reference its responses to Paragraphs 1 through 40 of the
10 Complaint.
11

12 42. Lilly denies the allegations contained in Paragraph 42 of the Complaint.
13

14 43. Lilly denies the allegations contained in Paragraph 43 of the Complaint.
15

16 44. Lilly denies the allegations contained in Paragraph 44 of the Complaint.
17

18 **FIFTH CAUSE OF ACTION**

19 **[Breach of Implied Warranty]**

20 45. Lilly incorporates by reference its responses to Paragraphs 1 through 44 of the
21 Complaint.
22

23 46. Lilly denies the allegations contained in Paragraph 46 of the Complaint, except
24 admits that it researched, tested, developed, manufactured, marketed, and sold Zyprexa to
25 independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in
26 accordance with applicable laws and regulations, and for its approved indications with FDA-
27 approved warnings regarding the risks and benefits of the medication.
28

47. Lilly denies the allegations contained in Paragraph 47 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 47 of the Complaint relating to plaintiffs' and plaintiffs' alleged agents' reliance.

48. Lilly denies the allegations contained in Paragraph 48 of the Complaint.

49. Lilly denies the allegations contained in Paragraph 49 of the Complaint.

SIXTH CAUSE OF ACTION

[Fraudulent Concealment]

50. Lilly incorporates by reference its responses to Paragraphs 1 through 49 of the Complaint.

51. Lilly denies the allegations contained in Paragraph 51 of the Complaint, except admits that it had a duty to exercise reasonable care in the research, testing, development, manufacturing, labeling, marketing, and sale of Zyprexa. Lilly denies that it breached such a duty.

52. Lilly denies the allegations contained in Paragraph 52 of the Complaint, except admits that it had a duty to exercise reasonable care in the research, testing, development, manufacturing, labeling, marketing, and sale of Zyprexa. Lilly denies that it breached such a duty.

53. Lilly denies the allegations contained in Paragraph 53 of the Complaint.

54. Lilly denies the allegations contained in Paragraph 54 of the Complaint.

55. Lilly denies the allegations contained in Paragraph 55 of the Complaint.

1 56. Lilly denies the allegations contained in Paragraph 56 of the Complaint.
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3 57. Lilly denies the allegations contained in Paragraph 57 of the Complaint.
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5 58. Lilly denies the allegations contained in Paragraph 58 of the Complaint.
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7 59. Lilly denies the allegations contained in Paragraph 59 of the Complaint.
8

9 **PRAYER FOR RELIEF**
10

11 Lilly incorporates by reference, as though fully set forth herein, its answer to every
12 allegation contained in each paragraph of the Complaint. Lilly denies that plaintiffs are entitled to
13 any of the requested relief set forth in Paragraphs 1 through 11 of plaintiffs' Prayer for Relief.
14

15 WHEREFORE, defendant Eli Lilly and Company requests that plaintiffs' Complaint,
16 and all claims alleged therein, be dismissed with prejudice; that Lilly be awarded its costs,
17 disbursements, and attorney's fees incurred in the defense of this action; and that Lilly be granted
18 any other relief to which it may be entitled.
19

20 **PREAMBLE TO AFFIRMATIVE DEFENSES**
21

22 Lilly reserves the right to rely upon any of the following or any additional defenses to each
23 claim for relief asserted by plaintiffs to the extent that such defenses are supported by information
24 developed through discovery or by evidence at trial.
25

26 **FIRST AFFIRMATIVE DEFENSE**
27

28 The Complaint fails to state a claim upon which relief can be granted against Lilly.
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SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the statute of limitations.

THIRD AFFIRMATIVE DEFENSE

Some or all of plaintiffs' claims are barred by the learned intermediary and/or sophisticated user doctrines. At all relevant times herein, plaintiffs' prescribing physicians were in the position of learned intermediaries and/or sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of Zyprexa.

FOURTH AFFIRMATIVE DEFENSE

The injuries, damages, and losses alleged in the Complaint, none being admitted, were caused in whole or in part by the negligence of the plaintiffs and/or others, over whom Lilly exercised no control, had no opportunity to anticipate or right to control, and with whom Lilly had no legal relationship by which liability could be attributed to it because of the actions of the plaintiffs and/or others, which, by comparison, was far greater than any conduct alleged as to Lilly.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged loss, damage, injury, harm, expense, diminution, or deprivation alleged, if any, was caused in whole or in part by plaintiffs' failure to exercise reasonable care and diligence to mitigate their alleged damages.

1 **SIXTH AFFIRMATIVE DEFENSE**
2

3 Plaintiffs' claims are preempted by federal law in that Zyprexa was manufactured and
4 labeled in a manner consistent with the state of the art at the pertinent time and approved by the
5 FDA.

6
7 **SEVENTH AFFIRMATIVE DEFENSE**
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9 Some or all of plaintiffs' claims are barred by the doctrines concerning unavoidably unsafe
10 products, including, but not limited to, the operation of comments j and k to Section 402A of the
11 Restatement (Second) of Torts and/or barred by the Restatement (Third) of Torts.

12
13 **EIGHTH AFFIRMATIVE DEFENSE**
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15 Plaintiffs' breach of warranty claims are barred because there is no privity of contract
16 between plaintiffs and Lilly; plaintiffs failed to give timely notice of any alleged breach of warranty
17 to Lilly; plaintiffs did not reasonably rely upon any alleged warranty; plaintiffs failed to satisfy all
18 conditions precedent or subsequent to the enforcement of such warranty; and the warranty was
19 appropriately disclaimed, excluded, or modified.

20
21 **NINTH AFFIRMATIVE DEFENSE**
22

23 Plaintiffs' claims are barred in whole or in part by the applicable provisions of the United
24 States Constitution, the California Constitution, and/or the applicable Constitution of any other State
25 or Commonwealth of the United States whose laws might be deemed controlling in this case. These
26 provisions include, but are not limited to, the First Amendment to the Constitution of the United
27 States and/or Article I, Section 2 of the Constitution of the State of California because Lilly's
28 commercial speech regarding Zyprexa was neither false nor misleading.

TENTH AFFIRMATIVE DEFENSE

Lilly alleges that plaintiffs were fully informed of the risks of the use of the product made the subject of this action by the treating physicians, and the informed consent given by plaintiffs is pleaded as an affirmative defense.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claim for punitive damages violates, and it is therefore barred by, the Fourth, Fifth, Sixth, Eighth, and Fourteenth Amendments to the Constitution of the United States of America on grounds including the following:

a. It is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment to the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiff's satisfying a burden of proof that is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

b. the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment to the United States Constitution;

c. the procedures pursuant to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against a defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution;

d. the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due

1 Process Clause of the Fourteenth Amendment to the United States Constitution;

2
3 e. the procedures pursuant to which punitive damages are awarded result in the
4 imposition of different penalties for the same or similar acts, and thus violate the Equal Protection
5 Clause of the Fourteenth Amendment to the United States Constitution;

6
7 f. the procedures pursuant to which punitive damages are awarded permit the
8 imposition of punitive damages in excess of the maximum criminal fine for the same or similar
9 conduct, which thereby infringes upon the Due Process Clauses of the Fifth and Fourteenth
10 Amendments and the Equal Protection Clause of the Fourteenth Amendment to the United States
11 Constitution;

12
13 g. the procedures pursuant to which punitive damages are awarded permit the
14 imposition of excessive fines in violation of the Eighth Amendment to the United States
15 Constitution;

16
17 h. the award of punitive damages to plaintiffs in this action would constitute a
18 deprivation of property without due process of law; and

19
20 i. the procedures pursuant to which punitive damages are awarded permit the
21 imposition of an excessive fine and penalty.

22
23 **TWELFTH AFFIRMATIVE DEFENSE**

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25 With respect to plaintiffs' demand for punitive or exemplary damages, Lilly specifically
26 incorporates by reference all standards of limitations regarding the determination and enforceability
27 of punitive damages awards including, but not limited to, those standards of limitation which arose
28 in BMW of North America v. Gore, 517 U.S. 559 (1996), Cooper Industries, Inc. v. Leatherman

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1 Tool Group, Inc., 532 U.S. 424 (2001), and State Farm Mutual Automobile Ins. Co. v. Campbell,
2 538 U.S. 408 (2003).

3

4 **THIRTEENTH AFFIRMATIVE DEFENSE**

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6 Plaintiffs' claims are barred and/or this Court should defer this matter, in whole or in part,
7 pursuant to the doctrine of primary jurisdiction, in that the FDA is charged under the law with
8 regulating prescription drugs, including Zyprexa, and is specifically charged with determining the
9 content of the warnings and labeling for prescription drugs. The granting of the relief prayed for in
10 plaintiffs' Complaint would impede, impair, frustrate, or burden the effectiveness of such federal law
11 and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution.

12

13 **FOURTEENTH AFFIRMATIVE DEFENSE**

14

15 To the extent plaintiffs' claims are based on alleged misrepresentations made to the FDA,
16 such claims are barred pursuant to Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341
17 (2001).

18

19 **FIFTEENTH AFFIRMATIVE DEFENSE**

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21 The injuries or damages allegedly sustained by plaintiffs can be attributed to several causes
22 and, accordingly, should be apportioned among the various causes according to the respective
23 contribution of each such cause to the harm sustained, if any. If any liability is found against Lilly,
24 any such liability being expressly denied, then said liability will constitute 50% or less of the total
25 liability assigned to all persons liable, and, as such, the liability of Lilly to plaintiffs for non-
26 economic loss shall be limited, and shall not exceed Lilly's equitable share.

SIXTEENTH AFFIRMATIVE DEFENSE

Any verdict or judgment rendered against Lilly must be reduced by those amounts that have been, or will, with reasonable certainty, replace or indemnify plaintiffs, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, social security, worker's compensation, or employee benefit programs.

SEVENTEENTH AFFIRMATIVE DEFENSE

The provisions of California Civil Code § 1431.2 are applicable to the Complaint and each claim for relief therein.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for strict products liability based upon design defect are barred by California law, which holds that a pharmaceutical manufacturer's liability for a defectively designed drug shall not be measured by the standards of strict liability. Brown v. Superior Court (Abbott Laboratories), 44 Cal.3d 1049, 1061 (1988); see also, Armstrong v. Optical Radiation Corp., 50 Cal.App.4th 580, 595 (1996); Hufft v. Horowitz, 4 Cal.App.4th 8, 13-17 (1992).

NINETEENTH AFFIRMATIVE DEFENSE

Venue is improper in this judicial district.

TWENTIETH AFFIRMATIVE DEFENSE

The Complaint improperly joins plaintiffs to the causes of action asserted against Eli Lilly and Company because plaintiffs' right to relief, if any, does not arise out of the same transaction or series of transaction, and plaintiffs' claims do not involve common questions of fact or law.

WHEREFORE, Lilly respectfully requests that this Court enter judgment in favor of Lilly and against plaintiffs; dismiss plaintiffs' claims with prejudice; award Lilly its costs, disbursements, and attorney's fees incurred in the defense of this action; and grant Lilly such other relief as the Court may deem just and proper.

DATED: April 12, 2006.

REED SMITH LLP

By /s/ James Wood

James M. Wood
Nadia M. Bishop
Attorneys for Defendant
Eli Lilly and Company, a corporation

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38, Defendant Eli Lilly and Company hereby demands a trial by jury as to all issues so triable.

DATED: April 12, 2006.

REED SMITH LLP

By /s/ James Wood

James M. Wood
Nadia M. Bishop
Attorney for Defendant
Eli Lilly and Company, a corporation

REED SMITH LLP
A limited liability partnership formed in the State of Delaware

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CERTIFICATION OF INTERESTED ENTITIES AND PERSONS

Pursuant to Local Rule 3-16, the undersigned certifies that, as of this date, other than the named parties, there is no such interest to report.

REED SMITH LLP
A limited liability partnership formed in the State of Delaware

No.: C 06-1607 CW

1 DATED: April 12, 2006

2 REED SMITH LLP

3 By /s/ James Wood

4 James M. Wood
5 Nadia M. Bishop
6 Attorney for Defendant
7 Eli Lilly and Company, a corporation

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